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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/671,461	09/27/2000	Arne Staby	5784.210-US	6001

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NOVO NORDISK, INC.  
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EXAMINER

KAM, CHIH MIN

ART UNIT PAPER NUMBER

1653

DATE MAILED: 01/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application No.

09/671,461

Applicant(s)

STABY, ARNE

Examiner

Chih-Min Kam

Art Unit

1653

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 15 December 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY [check either a) or b)]**

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 15 December 2004. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet.

3. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: 4.

Claim(s) objected to: \_\_\_\_\_.

Claim(s) rejected: 2, 6 and 11-15.

Claim(s) withdrawn from consideration: \_\_\_\_\_.

8. ☐ The drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☐ Other: \_\_\_\_\_

Continuation of 2. NOTE: The amendment to the claims does not resolve the current issues under 35 USC 102(e). In the amendment of December 15, 2004, claims 6, 11, 12 and 15 have been amended; and new claims 16-21 have been added. Applicants' response has been fully considered, however, claims 2, 6, 11, 13 and 14 are rejected under 35 USC 102(e).

If applicants' amendment were entered, it would have the following response:

1. Claims 2, 6, 11, 13 and 14 remain rejected under 35 U.S.C. 102(e) as being anticipated by Korc et al. (US 2003/0103980 A1, priority date October 16, 1998).

Korc et al. teach GAG-containing forms of glypican-1 and syndecan-1 were purified by anion exchange chromatograph on DEAE-Sephacel equilibrated in buffer A (50 mM Tris-HCl, pH 8.0, 0.15 M NaCl, 0.1% triton X-100) (paragraphs [0019] and [0068], Fig. 5). Cell lysates containing glypican-1 or syndecan-1 in buffer B (50 mM Tris-HCl, pH 8.0, 0.15 M NaCl, 0.1% triton X-100, 1mM EDTA, 1 mg/ml pepstatin A, 1 mM PMSF) were loaded onto columns, and columns were eluted stepwise with buffer A, buffer C (50 mM Tris-HCl, pH 8.0, 0.25 M NaCl, 0.1% triton X-100), buffer D (50 mM Tris-HCl, pH 8.0, 6 M urea, 0.25 M NaCl, 0.1% triton X-100), and buffer E (50 mM sodium formate, pH 3.5, 0.2 M NaCl, 6 M urea, 0.1% triton X-100). After restoring the pH with 50 mM Tris-HCl, pH 8.0, 0.1% triton X-100, glypican-1 or syndecan-1 was eluted from the column with buffer F (50 mM Tris-HCl, pH 8.0, 0.75 M NaCl, 0.1% triton X-100) (claims 2, 11 and 14). The eluted material was diluted five fold with 50 mM Tris-HCl, pH 8.0, 0.1% triton X-100, concentrated, and clarified by filtration, and samples were then resuspended in buffer B and analyzed by immunoblotting (claim 6). The concentration of urea in the buffer is 6 M, which corresponds to the ratio of 1:1.8 of urea to water (claim 13). Since the peptide of glypican-1 or syndecan-1 is still bound to the anion exchange column when the column is eluted with buffers D and E containing 6 M urea, it is expected that the impurities have lower negative charges and less affinity toward the positively charged resin than the peptide (e.g., glypican-1) and are eluted from the column using buffers D and E containing 6 M urea.

In response, applicants indicate independent claims 2 and 4, step a) refers to washing the column at a certain pH to elute impurities and step b) then refers to eluting the peptide of interest from the column at the same or lower pH than in step a). Korc et al. teach that the buffers D and E applied sequentially to wash the DEAE column to remove impurities are at pH 8.0 and 3.5, respectively, and after the wash with buffer E, the pH is then adjusted back to pH 8.0 and that the peptide of interest (glypican or syndecan) is then eluted with buffer F (50 mM tris-HCl, pH 8.0, 0.75M NaCl, 0.1% triton X-100). Since buffer E is at pH 3.5 and the buffer used to elute the glypican is at pH 8.0, the method used by Korc does not meet the limitation of step b) of claims 2 and 4 that the pH used in step b) be the same or lower pH as the pH in step a) and hence cannot anticipate the claims.

The response has been considered, however, the argument is not found persuasive because the reference does teach washing the column to remove impurities at pH 8.0 (buffer D containing urea; step a); and the peptide of interest is then eluted with buffer F at pH 8.0 (step b), where buffer D and buffer F have the same pH, which meet the limitation of claim 2. Since the claimed method recites the method "comprising" steps a) and b), the extra washing step with buffer E can be included in the claimed method. Therefore, the reference anticipates the claimed method.

2. Claims 12 and 15 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Continuation of 3. Applicant's reply has overcome the following rejection(s): If entered, the rejection of claims 6, 11, 12 and 15 under 35 USC 112, second paragraph.

Continuation of 5. does NOT place the application in condition for allowance because: The amendment to the claims does not resolve current issues under 35 USC 102(e).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

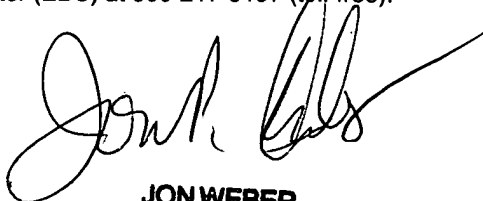
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached at 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.  
Patent Examiner

CMK

CMK  
January 11, 2005

  
JON WEBER  
SUPERVISORY PATENT EXAMINER